Exhibit A

PEGGY PENCE, PhD, RAC, FRAPS
EXPERT WITNESS REPORT

RE: ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of Ethicon, Inc., GYNECARE, AND JOHNSON & JOHNSON
(Collectively referred to in this Report as Ethicon)

reported quality of life outcomes. When these have been reported, there is little difference between surgical procedures using mesh and those without mesh, and the use of mesh is associated with additional complications, particularly mesh erosion.

Furthermore, most published reports of clinical trials have only included a short-term follow-up. Thus, Dr. Robinson's "Literature Review Conclusion Statement," provided following, in the Clinical Expert Report is inconsistent with the lack of long-term safety and efficacy studies in the literature: "The above data [referring to his literature review], taken together with any available pre-clinical data, are sufficient to demonstrate compliance with the essential requirements covering safety and performance of GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems under normal conditions of use. **No additional clinical data is required**."[406] (Emphasis added.) Moreover, this statement is contradicted by FDA's later issuance of orders mandating postmarket surveillance studies.

In my professional opinion, based on the information known or knowable to Ethicon, a reasonably prudent medical device manufacturer would have undertaken pro-actively the appropriate, controlled clinical studies to identify the patient population, if any, for which the potential risks were justified by the potential benefit in anatomic outcome, using the PROLIFT. Additionally, reasonably prudent efforts to manage risk would have included labeling changes, specifically, to add Warnings and Precaution to the Instructions for Use, including the following:

- Warning that patients may require additional surgical procedure(s) to repair mesh erosion, which may be debilitating;
- Warning that complications have been shown to be higher with mesh placement compared to traditional non-mesh repair;
- Precaution that while transvaginal repair with mesh may provide anatomic benefit compared to traditional, non-mesh POP repair, this may not result in better symptomatic results.

Because Ethicon judged the risk acceptable, no such actions were taken to manage the risks. In my professional opinion, Ethicon continued to market a product that was misbranded due to labeling issues, in particular, as a result of inadequate directions for use and inadequate warnings, and because the device was dangerous to health when used in the manner suggested in the labeling.[407]

IX. SUMMATION OF OPINIONS: STANDARD OF CARE AND DEVIATIONS

OPINION #1: Ethicon Marketed a Misbranded and Adulterated PROLIFT Device

The FDCA requires that a medical device be 510(k)-cleared[408] or approved[409] by FDA prior to introduction of the device into interstate commerce, except when a change made to an existing 510(k)-cleared device does not pose the potential to significantly affect the safety or

[406] ETH.MESH.01207154 at 170: *Id.*
[407] FDCA § 502(f)(1) and (2) (21 USC § 352).
[408] FDCA §§ 510(k), 513(i).
[409] FDCA § 515

effectiveness of the device or the intended use of the device.[410] In my professional opinion, Ethicon marketed a misbranded and adulterated PROLIFT device from the time of its product launch in early 2005 until 510(k) clearance was obtained.[411] Even thereafter, Ethicon continued to disseminate false and misleading information in the form of its IFUs, Patient Brochures and other marketing information with regards to the safety and effectiveness of the PROLIFT System.

OPINION #2: Ethicon Reported False and Misleading Information to FDA

During the review of the PROLIFT 510(k) (K071512/01), Ethicon failed to disclose to FDA known safety issues with the PROLIFT, as discussed above. Not only did Ethicon not disclose safety issues but Ethicon also reported to FDA that the PROLIFT did not introduce any new issues of safety or effectiveness as compared to the GYNEMESH predicate and "that surgeons can use the device without problems."[412] In my professional opinion, Ethicon submitted false and misleading information to FDA, in violation of the standard of care required of a medical device manufacturer.

OPINION #3: PROLIFT Misbranded - Failure to Warn and False or Misleading Labeling

Product labeling is a cornerstone of risk management. Its purpose is to provide the user with the information necessary to use the product safely and effectively. For this reason, a device manufacturer must implement label changes in a timely manner as soon as possible after notice of any issues that may impact the safety or effectiveness of the device.[413] While labeling for prescription devices is premised on the concept that prescription devices are not safe for use except under the supervision of a licensed practitioner and, accordingly, are exempt from the "adequate directions for use" requirements applicable to OTC devices,[414] prescription device labeling nevertheless is required to contain information adequate for a licensed practitioner to use the device safely and effectively for its intended use.[415] Required use information includes indications, effects, routes, methods, and any relevant hazards, contraindications, side effects, and precautions under which the device can be used safely.[416]

In my professional opinion, based on my review of the PROLIFT labeling history and the IFU and patient labeling information discussed in this report, Ethicon deviated from the standard of care required of a medical device manufacturer by marketing a product that was misbranded because of multiple labeling issues. Section 502 of the FDCA contains provisions on misbranding and the labeling issues that cause a product to be misbranded.

[410] 21 CFR § 807.81(a)(3).
[411] ETH.MESH.00748451: Substantial Equvalence Letter for Prolift and Prolift+M Total, Anterior, and Posterior Pelvic Floor Repair Systems, May 15, 2008.
[412] ETH.MESH.00372341 at 347: K071512 S02, submitted to Jiyoung Dang, FDA, 9/20/07.
[413] Bryan Lisa deposition, 12/19/11, 293:12-294:18.
[414] 21 CFR § 801.109
[415] 21 CFR § 801.109(c).
[416] 21 CFR § 801.109(d).